MULTI-ACTION ANTISEPTIC- cetylpyridinium chloride rinse Amazon.com Services LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Solimo 299.005 299AK-AL

claims

For better oral hygiene and fresher breath

active ingredients

Cetylpyridinium Chloride 0.07%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Stop use and ask a dentist if

- gingivitis, bleeding or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gun line, loose teeth or increased spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

if more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control center right away.

Directions

- adults and children 6 years & older: rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day
- do not swallow
- children 6 years to under 12 years of age: supervise use
- when used after brushng, rinse mouth with water first

• children under 6 years of age: do not use

Other information

this rinse is not intended to replace brushing or flossing

inactive ingredients

water, glycerin, flavor, poloxamer 188, sodium saccharin, propylene glycol, sodium benzoate, sucralose, benzoic acid, blue 1

disclaimer

This rinse may cause temporary staining to the sufrace of teeth. This is not harmful and adequate brushing may prevent its occurrence.

Adverse reactions

DISTRIBUTED BY:

Amazon.com Services LLC

Seattle, WA 98109

1-877-485-0385

2018 Amazon.com, Inc or its Affiliates. All rights reserved. Solimo and all related logos are trademarks of Amazon.com, Inc or its affiliates.

Principal Display Panel

Solimo

Multi Action

Antiseptic Rinse

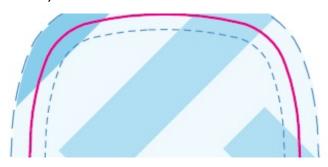
ANTIGINGIVITIS/ANTIPLAQUE

MOUTH RINSE

Fresh mint

Alcohol free

1L (33.8 FL OZ)



SOUMO

Multi Action Antiseptic Rinse

ANTIGINGIVITIS/ANTIPLAQUE MOUTH RINSE

Fresh mint Alcohol free

1L (33.8 FL OZ)

L0017604FA

MULTI-ACTION ANTISEPTIC

cetylpyridinium chloride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-299
Route of Administration	ORAL		

	Active Ingredient/Active Moiety				
ı	Ingredient Name	Basis of Strength	Strength		
	CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII: CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.7 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLOXAMER 188 (UNII: LQA7B6G8JG)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
BENZOIC ACID (UNII: 85KN0B0MIM)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C BLUE NO. 1 (UNII: H3K4/K31BD)			

Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:72288- 299-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/25/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/25/2018	

Labeler - Amazon.com Services LLC (128990418)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(72288-299)	

Revised: 4/2021 Amazon.com Services LLC